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# Fax Cover Sheet

**Date:** 01 Oct 2004

<b>To:</b> Angelia Collison	<b>From:</b> Theodore J. Criares
<b>Application/Control Number:</b> 10/080,876	<b>Art Unit:</b> 1617
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<b>Voice No.:</b> 212-588-0800	<b>Return Fax No.:</b> (703) 872-9306
<b>Re:</b> Action received 9/13/04	<b>CC:</b>

☒ **Urgent**    ☐ **For Review**    ☐ **For Comment**    ☐ **For Reply**    ☒ **Per Your Request**

**Comments:**

Forwarded herewith is a complete copy of the above Office Action.

**Number of pages 5 including this page**

## STATEMENT OF CONFIDENTIALITY

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## **CLAIMS 14-22 ARE PRESENTED FOR EXAMINATION**

Applicant's arguments filed May 19, 2004 and the Declarations of Brian R. Walker and Jonathan R. Seckl have been fully considered but they are not persuasive.

Applicant argues that there is sufficient compounds that are known inhibitors of 11 beta-hydroxysteroid dehydrogenase to those of ordinary skill in the art. The declarants aver that the skilled artisan would not have required any undue experimentation to practice the claimed invention and incorporate the references cited in the application as evidence thereof. However, a review of the accompanying remarks indicates that the compounds as taught in the references are unpredictable.

In the Monder and White article, at page 199, second full paragraph, it is disclosed that the inhibitory effect between steroids differs between tissues.

Applicant's claims are drawn to a method of reducing circulating fatty acids in adipose tissue in a patient. The patient, as set forth in claims 19-22, can be one suffering from obesity, insulin resistant, or both. There is a lack of guidance in the references submitted by the applicant that one of ordinary skill in the using any one of the compounds taught in the cited literature would be able to know that the compounds taught therein were capable of reducing circulating fatty acids in said patients without undue experimentation. As stated above the compounds in Table IV of the Moner and White reference have different activity in different tissues. One of ordinary skill in the art would have to choose, only after undue experimentation which of the compounds will have the desired effect on the specific tissue claimed. The reference stated above

clearly states that here are different criteria to which compounds have the inhibitory effect. See page 195 wherein it is stated:

“Steroids devoid of oxygen at C-11 are generally not inhibitors, or inhibit oxidation poorly.”

Therefore, the rejection under 35 U.S.C.112, first paragraph is deemed proper since not all inhibitors are known to act on various tissues effectively. Applicant's one compound does not support the variety of compounds within the claims without further undue experimentation by the skilled artisan. The rejection under 35 USC § 112 is *deemed proper and restated herein.*

*The Terminal Disclaimer filed May 19, 2004 in the subject application has been accepted by the United States Patent Office.*

***Claim Rejections - 35 USC § 112.***

Applicant's claims are drawn to a method of reducing circulating fatty acids (CLAIMS 14-20) and treating obesity, insulin resistance or obesity and insulin resistance (claims 21 and 22) by administering a compound which inhibits reductase activity of 11-Beta HSD1

Claims 14-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compound carbenoxolone compound does not provide enablement for all compounds which inhibit the reductase activity of 11-Beta-hydroxysteroid dehydrogenase in adipose tissue. There is a lack of compounds which would enable the skilled artisan to practice the invention. Only one compound has been identified by the applicants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the

invention commensurate in scope with these claims 14 and 15. Applicants' specification only identifies one compound which has the claimed activity, i.e. carbenoxolone.

Claims 16 and 17 are rejected since they read on rejected claims 14 and 15.

Therefore, applicants' generic claims 14, 15 and 18-22 are deemed to be beyond the scope of the enabled disclosure in the specification.

The prosecution of this application will be advanced if claims 16 and 17 are incorporated into claims 14.15 and 18-22.

None of the claims are allowed.


**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Criares whose telephone number is (571) 272-0625. The examiner can normally be reached on 6:30 A.M. to 5:00P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Theodore J. Criares  
Primary Examiner  
Art Unit 1617

TJC  
9/7/04